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Herbal medicine: summary for the public

Valerian essential oil

Valeriana officinalis L., aetheroleum

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of valerian essential oil. The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing valerian essential oil.

This summary is not intended to provide practical advice on how to use medicines containing valerian essential oil. For practical information about using valerian essential oil medicines, patients should read the package leaflet that comes with the medicine or contact their doctor or pharmacist.

What is valerian essential oil?

Valerian essential oil is the common name for the essential oil extracted from the underground parts of the plant *Valeriana officinalis* L.

Valerian essential oil is obtained by directing steam through the underground parts of the plant.

Herbal medicines containing valerian essential oil are usually available in liquid forms to be taken by mouth or used as bath additives.

Valerian essential oil may also be found in combination with other herbal substances in some herbal medicines. These combinations are not covered in this summary.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that, on the basis of its long-standing use, valerian essential oil can be used for relief of mild symptoms of mental stress and to aid sleep.

Valerian essential oil medicines should be used only in adults and adolescents over the age of 12 years. If symptoms continue during the use of the medicine, a doctor or a healthcare practitioner should be consulted. Detailed instructions on how to take valerian essential oil medicines and who can use them can be found in the package leaflet that comes with the medicine.

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What evidence supports the use of valerian essential oil medicines?

The HMPC conclusions on the use of these valerian essential oil medicines for the relief of mild symptoms of mental stress and to aid sleep are based on their 'traditional use'. This means that, although there is insufficient evidence from clinical studies, the effectiveness of these herbal medicines is plausible and there is evidence that they have been used safely in this way for at least 30 years (including at least 15 years within the EU). Moreover, the intended use does not require medical supervision.

The HMPC noted the lack of clinical studies with valerian essential oil medicines, but took into account the well documented use of this herbal medicine.

For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with valerian essential oil medicines?

Side effects have been reported with valerian essential oil medicines. These include nausea and abdominal cramps.

Patients with open wounds, skin problems, high fever, severe infections and severe heart and circulation problems should not have baths with valerian essential oil medicines.

Further information on the risks associated with these valerian essential oil medicines, including the appropriate precautions for their safe use, can be found in the monograph under the tab 'All documents' on the Agency's website: <u>ema.europa.eu/Find medicine/Herbal medicines for human use</u>.

How are valerian essential oil medicines approved in the EU?

Any applications for the licensing of medicines containing valerian essential oil have to be submitted to the national authorities responsible for medicinal products, which will assess the application for the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of valerian essential oil medicines in EU Member States should be obtained from the relevant national authorities.

Other information about valerian essential oil medicines

Further information on the HMPC assessment of valerian essential oil medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: <u>ema.europa.eu/Find medicine/Herbal medicines for human use</u>. For more information about treatment with valerian essential oil medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.